K071911

5. 510(k) Summary

SEP - 7 2007

Date of Summary	9 July 2007
Submitter/Contact Person	Richard O. Wood The **Wood Burditt** Group FDA Regulatory Counseling 1025 W. Everett Rd., Suite 100 Lake Forest, IL 60045 (ph) (847) 234-7500 x 203 (fax) (847) 574-0728 (email) rowood@woodburditt.com
Applicant	Innovision A/S Lindvedvej 75 DK-5260 Odense S Denmark Phone: +45 65 95 91 00 Fax: +45 65 95 78 00 info@innovision.dk www.innovision.dk
Device Name	Cardiopulmonary Exercise Testing Option to Innocor (referred to in this submission as "Cardiopulmonary Exercise Testing Option to Innocor," "Breath-by-Breath System," and "BbB System")
Common Name	Cardiopulmonary Exercise Testing System
Classification	*[Hemodynamic Measurements—Already Cleared K051907]* Computer, diagnostic, programmable Regulation Number: 21 CFR §870.1425 Product Code: DQK Panel Code: Cardiovascular Device Class: IIa *[Cardiopulmonary Exercise Testing Option]* Oxygen uptake computer Regulation Number: 21 CFR §868.1730 Product Code: BZL Panel Code: Anesthesiology Device Class: IIa

Legally Marketed Predicate Devices	The Cardiopulmonary Exercise Testing Option to Innocor is substantially equivalent in respect to the intended use, design and method of operation to: *Predicate Device No. 1* Name: Innocor 510(k) number: K051907 Manufacturer: Innovision A/S, Denmark *Predicate Device No. 2* Name: Ultima System 510(k) number: K061731 Manufacturer: Medical Graphics Corporation, MN
Device Description	Innocor is a compact point-of-care device intended to be used for non-invasive measurement of a) cardiac output (CO) and other hemodynamic parameters utilizing inert gas rebreathing (IGR) technology, and b) metabolic parameters including oxygen uptake by means of a breath-by-breath gas exchange method. The Breath-by-Breath option provides measurements of gas exchange parameters including oxygen uptake (VO_2), carbon dioxide excretion (VCO_2), ventilation (V_E) and end-tidal gas concentrations plus a number of derived parameters. These parameters are determined by simultaneous measurements of the respiratory flow and gas concentrations when breathing ambient air. The respiratory flow is measured by means of a differential pressure type flowmeter (pneumotachometer) placed between the respiratory valve unit and the patient. The gas exchange calculations are carried out online for each breath between the rebreathing tests. This gives the opportunity to perform an incremental exercise test on a bicycle ergometer or treadmill and measure the progress of cardiac function, pulmonary function and gas exchange at the same time.
Intended Use and	A cardiopulmonary exercise testing option is available for

Indications	Innocor. This option provides breath-by-breath measurements of flow, oxygen uptake and carbon dioxide production. It is intended to measure oxygen uptake (metabolic rate) and related parameters to objectively and non-invasively assess cardiac and pulmonary function at rest and during exercise. With the cardiopulmonary exercise testing option, Innocor provides values for: Main metabolic parameters: ☐ Oxygen uptake ☐ Carbon dioxide excretion ☐ Expiratory minute ventilation Calculated/derived parameters: ☐ Oxygen uptake per kg ☐ Respiratory exchange ratio ☐ Alveolar ventilation ☐ Anatomical dead space (Fowler dead space) ☐ Tidal volume ☐ Respiratory rate ☐ End-tidal concentration of oxygen ☐ End-tidal concentration of carbon dioxide ☐ Expiratory quotient / ventilatory equivalent for oxygen ☐ Expiratory quotient / ventilatory equivalent for carbon dioxide And the following calculated parameters after an incremental exercise test: ☐ Anaerobic threshold ☐ Respiratory compensation ☐ Rest values

	□ Values at AT point □ Values at max exercise
Performance Testing	The Cardiopulmonary Exercise Testing Option to Innocor has been shown by bench testing to be substantially equivalent in respect to its intended use to measure metabolic parameters on a breath-by-breath basis to the legally marketed predicate device Medical Graphics Ultima System, K061731.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Innovision A/S
c/o Mr. Richard O. Wood
Sponsor Representative
The Wood Burditt Group LLC
1025 Everett Road, Suite 100
Lake Forest, IL 60045

Re: K071911
Trade Name: Innocor, Models INN00400 and INN00500
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 29, 2007
Received: September 5, 2007

Dear Mr. Wood:

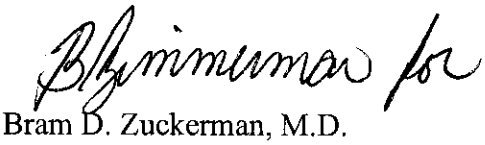
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K071911

Device Name: Cardiopulmonary Exercise Testing Option to Innocor

Indications for Use:

A cardiopulmonary exercise testing option is available for Innocor. This option provides breath-by-breath measurements of flow, oxygen uptake and carbon dioxide production. It is intended to measure oxygen uptake (metabolic rate) and related parameters to objectively and non-invasively assess cardiac and pulmonary function at rest and during exercise. With the cardiopulmonary exercise testing option, Innocor provides values for:

Main metabolic parameters:

- Oxygen uptake
- Carbon dioxide excretion
- Expiratory minute ventilation

Calculated/derived parameters:

- Oxygen uptake per kg
- Respiratory exchange ratio
- Alveolar ventilation
- Anatomical dead space (Fowler dead space)
- Tidal volume
- Respiratory rate
- End-tidal concentration of oxygen
- End-tidal concentration of carbon dioxide
- Expiratory quotient / ventilatory equivalent for oxygen
- Expiratory quotient / ventilatory equivalent for carbon dioxide

And the following calculated parameters after an incremental exercise test:

- Anaerobic threshold
- Respiratory compensation
- Rest values
- Values at AT point
- Values at max exercise

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071911